In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-0065V

UNPUBLISHED

K.P., Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Originally Filed: May 25, 2022 Refiled in Redacted Form: August 9, 2022 Special Processing Unit (SPU); Ruling on Entitlement; Findings of Fact; Severity; Localized Injury to Shoulder; Tetanus-Diphtheria-Acellular Pertussis (Tdap); Shoulder Injury Related to Vaccine Administration (SIRVA).

John Robert Howie, Howie Law, PC, Dallas, TX, for Petitioner.

Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 15, 2019, K.P. filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that as a result of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine received on September 12, 2016, she suffered a shoulder injury related to vaccine administration ("SIRVA") as defined on the Vaccine Injury Table (the "Table").

[1] When this decision was originally filed the undersigned advised his intent to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner filed a timely motion to redact certain information. This decision is being reissued with Petitioner's name redacted to her initials Except for those changes and this footnote, no other substantive changes have been made. This decision will be posted on the court's website with no further opportunity to move for redaction.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Petition (ECF No. 1) at Preamble. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters. After a full review of the evidence, I find it most likely that Petitioner's injury was limited to her left shoulder; that the injury and its residual effects lasted for more than six months; and that she is otherwise entitled to compensation. Accordingly, Petitioner's Motion to Deem SIRVA Table Elements are Satisfied (ECF No. 32) is granted.

I. Relevant Procedural History

As referenced above, Petitioner initiated her claim, accompanied by the requisite supporting documentation (filed as Exs. 1-14), in January 2019.[3] She filed updated records (Exs. 15-17) approximately one year later. The parties engaged in settlement discussions from December 2019 – July 2020, before reaching an impasse. Status Reports (ECF Nos. 18, 21-26). Thereafter, in December 2020, Respondent filed his formal report opposing compensation, contending that (1) Petitioner had not established the statutory "severity" requirement of six or more months of injury-related sequelae,[4] and (2) Petitioner's pain was not limited to the shoulder in which the vaccine was administered. Rule 4(c) Report (ECF No. 29) at 5-6 (citing Vaccine Act Section 11(c)(1)(D)(i); 42 C.F.R. § 100.3(c)(10)).

On April 22, 2021, Petitioner filed a supplemental affidavit (Ex. 19)[5] and a Motion to Deem SIRVA Table Elements are Satisfied (ECF No. 32). On May 13, 2021, Respondent filed his Response (ECF No. 34). Petitioner filed her Reply (ECF No. 35) the same day. The matter is ripe for adjudication.

II. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record.

[3] The claim was originally assigned to then-Chief Special Master Dorsey (now Special Master Dorsey), in her purview overseeing the SPU. In early October 2019, the case was reassigned to me as the current Chief Special Master.

[4] Petitioner does not allege, nor would the evidence support, either alternative for establishing the severity requirement: that the alleged injury resulted in death, or "inpatient hospitalization and surgical intervention." Section 11(c)(1)(D)(ii), (iii).

[5] As identified in the docket text, Bates-stamping, and Petitioner's briefing.

Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may

be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. Factual Evidence

A. Medical Records

Upon receiving the subject vaccination, K.P. was 26 years old. She did not have a primary care provider ("PCP") and she only periodically sought urgent care for issues which are irrelevant to this claim. *See generally* Exs. 3-5; Ex. 6 at 22-139; Ex. 9 at 5-8; Ex. 10 at 11.[6] Upon discovering that she was pregnant (with an expected due date in early November 2016), Petitioner began prenatal care at Steward Medical Group and St. Elizabeth's Medical Center. Exs. 8-9.

In August 2016, Petitioner transferred her medical care to Massachusetts General Hospital in Waltham, Massachusetts (hereinafter "MGH-Waltham"). The new patient evaluation was conducted by obstetrician-gynecologist ("OB-GYN") Rebecca Kolp, M.D. Ex. 10 at 12-35. The following month (on September 12, 2016), Petitioner received the subject Tdap vaccination in her left deltoid muscle, during another prenatal appointment. Ex. 10 at 44. At that time, Dr. Kolp also discussed childbirth classes; entered a referral to physical therapy ("PT") for pelvic pain; and prescribed a nebulizer for "chest tightness." *Id.* at 45.[7]

Fourteen (14) days after vaccination, on September 26, 2016, Petitioner telephoned the OB-GYN practice, reporting that she "had a TDAP shot how [sic] weeks ago and is still having severe pain in her arm." Ex. 10 at 56. She could not perceive any

[6] *Accord* Petition at ¶ 2 (stating that Petitioner was in good health and had "never suffered any sort of joint problems, muscle problems, injury, trauma, or pain in her left shoulder or left upper arm"); Rule 4(c) Report at 2 (stating that the past medical history appeared to be non-contributory).

[7] Two days later, Petitioner called the OB-GYN practice to follow up on the nebulizer prescription. Ex. 10 at 50, 52. These records do not address the presence or absence of left shoulder pain.

bruising or swelling. *Id.* at 57. The pain was worse after sleeping and she was having difficulty "mobiliz[ing]" the shoulder. *Id.* A registered nurse recommended Tylenol and alternating heat and ice until the next scheduled appointment with Dr. Kolp on October 3rd. *Id.* Two days later, on the morning of September 28th, Petitioner called the OB-GYN practice back to report that despite following the nurse's instructions, she had been experiencing worsening pain. Ex. 10 at 68. She was "tearful" on the phone and was added onto that day's schedule. *Id.*

When Petitioner presented to the OB-GYN practice that afternoon, a different nurse recorded Petitioner's temperature and her history of left shoulder pain beginning with the Tdap vaccination and worsening, as well as her current "inability to lift her arm now"; and that she "fe[lt] best when the arm is resting at her side." Ex. 10 at 60. Petitioner was not evaluated by her regular OB-GYN, but by Uchechi Amy Wosu, M.D.,[8] who recorded: "severe pain in her left shoulder radiating to her fingers, especially with movement." *Id.* Dr. Wosu also recorded: "Left shoulder and forearm pain after Tdap vaccine. Concern for irritation of musculocutaneous nerve, maybe ulnar nerve." *Id.* at 61. Dr. Wosu "request[ed] neurology consult ASAP. Pt wanted relief ASAP." *Id.* at 60. This encounter's documentation is limited to a referral order (signed that day at 2:41 p.m.) and progress notes (signed at 2:55 p.m.). *Id.* There is no review of systems or physical exam.

On October 3, 2016, Petitioner presented to neurologist Dinesh Nair, M.B.B.S., Ph.D., at the MGH main campus in Boston, Massachusetts. Ex. 13 at 3-5. She reported that the Tdap was "the most painful shot she ever received," and while she initially expected the pain to resolve, it had continued "mainly in the left shoulder and arm," aggravated by "anything that involves shoulder movements." *Id.* at 3. On physical exam, proximal strength testing and lifting her left arm above her head were both limited by pain. *Id.* at 5. The neurologist could not "appreciate any clear weakness" or determine "whether her range of motion [was] intact" due to the pain. *Id.* Reflexes and sensation were normal. *Id.* No joint swelling, redness, or tenderness were observed. *Id.* The neurologist documented spending 60 minutes with Petitioner and her husband, with approximately half spent the nature of symptoms and likely etiology – but he did not record any diagnosis more specific than "left upper arm pain with arm movements." *Id.* He did not see any evidence suggesting an abscess or local pathology. *Id.* Given that Petitioner's pain was "severely limiting her activities and she want[ed] to be fine when the baby arrive[d]", the neurologist ordered an MRI of her left shoulder, which would "hopefully… see enough of the deltoid muscle… to rule out focal pathology." *Id.*

[8] Petitioner initially characterized Dr. Wosu as "her obstetrician," Petition at ¶ 6; *accord* Rule 4(c) Report at 2; Response at 2. However, they had no previous encounters, and the record establishes that Petitioner's regular OB-GYN was Dr. Kolp.

Also on October 3rd, Petitioner underwent an initial PT evaluation for a two-month history of pregnancy-related pelvic pain, which caused difficulty walking and standing and was keeping her out of work. Ex. 10 at 72. The therapist recommended a brace and three further PT sessions prior to delivery. Petitioner also reported "left shoulder pain since undergoing Tdap injection 9/12/16." *Id*. That same day, she telephoned the OB-GYN practice to report continued "pain at the Tdap injection site." *Id.* at 86.

On October 4, 2016, Petitioner underwent the MRI for evaluation of "left shoulder pain; decreased range of motion of left shoulder; musculoskeletal arm pain." Ex. 10 at 91-92. It visualized mild depression of the posterior superior humeral head; underlying bone marrow edema; and "focal thickening and increased signal of the infraspinatus tendon with adjacent subacromial/ subdeltoid bursal inflammation." *Id.* at 93. The MGH-Waltham radiologist, Frank J. Simeone, M.D., recommended reviewing the clinical history for any recent subluxation or dislocation. *Id.* In the absence of any such history, the posterior shoulder findings were likely the sequela of "a remote prior Hill-Sachs fracture" and "inflammatory changes related to the flu shot." *Id.* at 94. That evening, the neurologist "spoke with [K.P.] about the MRI results," but there is no record of his specific assessment, diagnosis, or any further encounters. *Id.* at 93. Afterwards at the neurologist's direction, Petitioner telephoned the OB-GYN practice to arrange an orthopedics consult. *Id.* at 101, 103.

On October 7th,[9] an orthopedics physician assistant ("PA") at MGH-Waltham conducted an "evaluation of the left shoulder." Ex. 13 at 9. The PA recorded the history of an "incredibly painful" Tdap injection and "severe pain" ever since, particularly "when she moves it in any direction." *Id.* The PA recorded that the pain was currently 9/10 with a SSV (subjective shoulder value) of 10-20%. *Id.* The physical exam documented normal sensation; "difficulty with range of motion and manual muscle testing due to her pain level" at the shoulder; and weakness in both external and internal rotation. *Id.* In comparison, the left elbow had full range of motion. *Id.* at 10. The PA recorded a diagnosis of "left shoulder pain and weakness after recent Tdap injection." *Id.* at 9. She added that the symptoms were "consistent with axillary neurapraxia[10] as a result of the injection," which

[9] Respondent inadvertently stated that this encounter occurred on October 11th. Rule 4(c) Report at 3; Response at 3. But the PA only *signed* the progress note on that date.

[10] The axillary nerve originates in the posterior cord of the brachial plexus. Its branches are the lateral brachial cutaneous nerve and muscular rami. Its distribution is the deltoid and teres minor muscles and the skin of the arm covering the deltoid muscle. Its modalities are motor and general sensory. *Dorland's Illustrated Medical Dictionary Online* (hereinafter "*Dorland's*").

Neurapraxia is defined as failure of conduction in a nerve in the absence of structural changes, due to blunt injury, compression, or ischemia; return of function normally ensues. *Dorland's*.

would "likely resolve with time." *Id.* at 10. The PA noted that Petitioner was understandably anxious and was unable to take non-steroidal anti-inflammatory drugs ("NSAIDs") during pregnancy. *Id.* The PA did not believe that a cortisone injection at that time would be beneficial and planned only: "Physical therapy… to help to maintain motion as her nerve recovers with rest and time. She'll follow up after delivery of [sic?] her shoulder symptoms continue." *Id.*; *see also* Ex. 10 at 110 (OB-GYN referral for PT). There are no further records from this PA or any other orthopedic specialist.

On October 17, 2016, Petitioner returned to the same physical therapist. Ex. 10 at 121. Her pelvic pain was slightly improved despite not obtaining the recommended brace due to the cost. *Id.* The session was focused on assessing the left shoulder. *Id.* Passive and active range of motion were both limited. *Id.* There was "breakaway weakness possibly due to pain." *Id.* The therapist's assessment was "impaired shoulder ROM, strength, and function possibly due to inflammation surrounding injection and RTC [rotator cuff] tendonitis." *Id.* She provided a home exercise program ("HEP") to address active range of motion; scapular retraction, side bend stretching, and external rotation. *Id.* Petitioner would follow up in November or adjust the appointment as needed. *Id.* There are no further records from this PT practice.

That same day, Dr. Kolp recorded that Petitioner "still ha[d] pain in her [left] arm but is doing better." Ex. 10 at 126. She was "getting use[d] to" the pain and had received "exercises to help with this" from the physical therapist. *Id.* A seasonal flu vaccine was administered in Petitioner's right (opposite) deltoid. *Id.*[11] On October 24th, an OB-GYN nurse recorded that Petitioner's "[l]Left arm is feeling better," but she was having painful contractions at night. Ex. 10 at 132. Petitioner was thereafter hospitalized for the birth of her first child from October 31st – November 3rd. Ex. 13 at 13-42. She had no complaints at the first post-partum visit with Dr. Kolp on December 21, 2016. Ex. 10 at 148-49.

The following year, on January 7, 2017, and again on April 7, 2017, Petitioner obtained emergency care for ruptured ovarian cysts. Ex. 14 at 4-35, 36-64; *see also* Ex. 10 at 153-56, 167-74 (OB-GYN records). The medical records from this time period generally do not address the presence or existence of left shoulder pain. The one exception is on March 31, 2017, when Dr. Kolp authorized another referral to PT for left shoulder pain, attaching the October 2016 MRI. Ex. 10 at 158-60. (This date was more than six months after Petitioner's alleged onset).

[11] The immunization history carried forward in the medical records incorrectly states that this flu vaccine was administered in Petitioner's *left* deltoid, on October *27th*. Ex. 10 at 125. The parties agree that these details are incorrect. *See, e.g.*, Rule 4(c) Report at 3; Response at 3.

On April 26, 2017, Petitioner presented to a new PCP, Yvonne Wilson, M.D. Ex. 11 at 1-4. They discussed multiple complaints including asthma, ovarian cysts, weight gain, exercise intolerance, fatigue, headaches, sleep disturbance, and "left shoulder pain since September 2016." *Id.* at 3. While a physical exam documented a normal musculoskeletal system including "normal movement of all extremities," Dr. Wilson referred Petitioner to PT for left shoulder pain. *Id.* at 3-4.

At a May 11, 2017, initial evaluation at the Gemini PT practice, Petitioner reported left shoulder pain since the September 2016 injection. Ex. 12 at 2. It was "slowly improving but still… causing difficulty sleeping, dressing, brushing hair, lying down," and currently rated 3/10. *Id.* The therapist documented loss of strength, loss of range of motion, pain, positive impingement signs, and tenderness. *Id.* The assessment was "possible bursitis/ tendonitis… of SS [supraspinatus] more so than IS [infraspinatus] tendon." *Id.* She was planned for two PT sessions per week for four weeks, in addition to home exercises. *Id.* at 2-3. Petitioner reported some improvement at PT on May 16th, *see id.* at 4-5. She did attend any further PT sessions.

Over approximately the next two years, Petitioner periodically saw her OB-GYN for concerns including pelvic pain; ovarian cysts; testing for the BRCA gene; and pregnancy with a second child, delivered to term in late August 2018. Ex. 10 at 176-441; *see also* Exs. 16-17. Within these medical records, the problem list continued to include "decreased range of motion of left shoulder" which was first noted on October 4, 2016. However, there was no documentation of ongoing complaints or physical examinations of the left shoulder or arm. Also of note, Petitioner was recorded as receiving a flu vaccine in her left deltoid on January 22, 2018, and a Tdap vaccine in her left deltoid on June 4, 2018. Ex. 10 at 229, 239; *id.* at 315, 317, 323.[12]

On July 12, 2019, Petitioner presented to another primary care practice, Seacoast Medical Associates. Ex. 15 at 3-4. She reported not being to a doctor's appointment for "several years," while caring for a baby and a toddler, as well as depression "due to new separation from her husband last week." *Id.* at 3. She had "no specific concerns, just wanted to get started taking care of herself," but also mentioned "Left shoulder pain / sees PT and chiro." *Id.* However, the review of systems and physical exam were documented to be unremarkable, including normal sensation and strength in all extremities. *Id.*

[12] These records were specifically noted at the initial status conference in April 2019. *See* Scheduling Order (ECF No. 10). Neither party has submitted additional evidence or briefing regarding these subsequent vaccinations and their relevance to either entitlement or damages.

Petitioner was only instructed to undergo lab work, see a psychiatrist for depression, and follow up in six months. *Id.* at 3-4. No further medical records have been filed.[13]

B. Affidavits

K.P. recalls that upon receiving the September 12, 2016, Tdap vaccination, she developed considerable pain and soreness in her left shoulder and upper arm muscles. Ex. 1 at ¶ 1. She initially assumed that the pain was a typical and temporary side effect, but it instead worsened, to the point where she required medical attention before her next scheduled prenatal appointment. *Id.* at ¶¶ 1,2 6.

Petitioner recalls "describ[ing] my pain as severe… radiat[ing] from my left shoulder, down my arm, to my fingers" upon meeting with Dr. Wosu. Ex. 1 at ¶ 7. She recalls that Dr. Wosu elected not to perform a physical exam due to the severity of her pain, that the encounter lasted "only a few minutes," and that she did not understand why Dr. Wosu entered a referral to a neurologist rather than an orthopedist. Ex. 19 at ¶ 5. Petitioner insists that her pain was located in her left shoulder and upper arm, was worse with movement, and never involved "any sort of numbness or tingling." *Id.* at ¶ 15.

Petitioner was "absolutely miserable" due to the persistent shoulder pain; resulting sleep disruption and anxiety; lack of relief from Tylenol, ice, and heat; and lack of other treatment options, including NSAIDS such as ibuprofen, leading up to her first child's birth in early November 2016. Ex. 19 at ¶¶ 2-4.

Over the next several months, Petitioner recalls focusing on her infant, a stepchild with special needs, and her own other medical issues. Ex. 1 at ¶ 14; Ex. 19 at ¶¶ 9-10. She lived an hour away from the MGH PT clinic. Ex. 19 at ¶ 11. She was able to meet with a new PCP and a new physical therapist in spring 2017 only because her husband was temporarily unemployed and available to care for the children. *Id.* at ¶ 12. She did not seek further medical treatment due to additional personal circumstances including the birth of her second child, the dissolution of her marriage, and financial constraints. *Id.* at ¶¶ 13-14. Petitioner avers that her left shoulder pain never completely resolved, but it was manageable with ibuprofen throughout this time. *Id.* at ¶ 14.

[13] *But see* Motion at 25 (citing chiropractic records, identified as Ex. 18, which do not appear to have been filed); Response at n. 2 (stating that any such outstanding records are unlikely to change Respondent's analysis regarding entitlement).

IV. Findings of Fact

A. Severity

The threshold issue to be resolved is whether K.P. has demonstrated that she suffered "residual effects or complications of [the injury alleged for more than six months after the administration of the vaccine," as required for eligibility under the Vaccine Program. Section 11(c)(1)(D)(i).

As Respondent points out, in October 2016, within the first month after vaccination, an obstetrician and a nurse both documented that Petitioner's left shoulder was feeling "better" and that a left shoulder injury is not documented again until approximately five months later.[14] However, as Petitioner notes, "better" does not clearly signify a *resolution* of symptoms. The record ultimately best supports the conclusion that Petitioner was feeling *comparatively* better than before, because she had recently undergone PT and received home exercises that would help to manage her pain. Moreover, because the left shoulder injury remained present at that time, Petitioner requested, and the obstetrician agreed that a flu vaccine would be administered in her *other* arm. Petitioner had also been told that other treatment measures, such as a steroid injection, were unlikely to be beneficial and that her injury was likely to resolve over time.

Respondent also stresses the fact that in April 2017, the new PCP Dr. Wilson documented a normal physical exam. Rule 4(c) Report at 4, 7. But that is outweighed by Dr. Wilson's referral to PT for left shoulder pain, and the resulting evaluation which was more focused and yielded objective findings of a similar shoulder injury.

While the medical records over the subsequent months do not document a continuing left shoulder injury, those records are from emergency providers and specialists focused on the evaluation and treatment of more immediate concerns – chiefly childbirth, post-partum care, and ovarian cysts. It is not necessarily evident that Petitioner would have raised, or that her providers would have independently detected, an unrelated injury during these encounters. Petitioner has also provided a reasonable explanation (which is not contradicted by the medical records) that she was able to self-manage her pain by taking non-prescription ibuprofen during this time.

Thus, despite the gap in documentation, the spring 2017 medical records reflect familiar findings of pain and restricted range of motion centered at the left shoulder; a consistent history relating back to the September 2016 Tdap vaccination and the earlier course of treatment; and no suggestion of an alternate cause or aggravation. Ex. 10 at

[14] The gap in documentation specifically runs from the obstetrics records on October 24, 2016, to the obstetrics referral for PT on March 31, 2017.

158-60; Ex. 11 at 1-4; Ex. 12 at 2-3. Moreover, there is no evidence of a potential alternative cause. There is preponderant evidence that her injury and residual effects lasted through at least May 2017, and therefore severity is established.

B. Injury Limited to Shoulder

The second disputed issue is whether K.P.'s "pain and reduced range of motion are limited to the [left] shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(3)(10)(iii).

Respondent emphasizes that at the first medical encounter, Petitioner reported that her severe pain also involved her left forearm and left hand. Ex. 10 at 60. Of course, that record does not include an objective physical examination or other explanation from the provider, who did not have expertise in evaluating such complaints. The medical records also document Petitioner's worsening pain, lack of relief, and distress at this time – supporting that her characterization may well have been "hyperbole." Brief at 18. Nevertheless, this does stand as Petitioner indicating pain outside the area required for a successful SIRVA injury.

There is no subsequent evidence of an injury extending beyond the shoulder, however. A neurologist did not record any findings, diagnosis, studies, or treatment that would indicate an injury within his area of specialty. An MRI – ordered to evaluate left shoulder pain and decreased range of motion, characterized as "musculoskeletal" pain – indeed revealed "inflammatory changes related to the flu shot." Ex. 10 at 91-94. Thus, the weight of the evidence is limited to the relevant area (the shoulder), even if initially Petitioner reported other pain (which would not be actionable as a SIRVA sequela, most likely, had it persisted). *Accord Werning v. Sec'y of Health & Hum. Servs.*, No. 18-0267V, 2020 WL 5051154 (Fed. Cl. Spec. Mstr. July 27, 2020) (concluding that the petitioner established this SIRVA requirement despite limited complaints of pain traveling to the elbow and hand).

There is also a record from October 2016 stating that the Tdap vaccine caused an axillary nerve injury. Ex. 13 at 9-10. However, that assessment was offered by an orthopedics PA, without direct consultation with the neurologist who would be more qualified to make that assessment. The PA did not document any findings extending beyond the left shoulder, and confirmatory NCS/EMG testing was never ordered. Thus, the possibility that Petitioner's injury was not limited to the shoulder was never subsequently corroborated.

Petitioner also argues that in passing 42 C.F.R. § 100.3(c)(3)(10)(iii), the Secretary of Health and Human Services (the "Secretary") did not intend to exclude an injury otherwise consistent with SIRVA "with symptoms extending beyond the area of the affected shoulder." Motion at 20-21. To some degree, this argument misstates some of the relevant rulemaking history. For in establishing that criterion, the Secretary emphasized that a SIRVA must be "*localized* to the shoulder in which the vaccine is administered." Revisions to the Vaccine Injury Table on Jan. 19, 2017, 82 Fed. Reg. 6294, 6296 (emphasis added).[15] This wording is admittedly more restrictive than stating, for example, that a SIRVA must "originate" or be "centralized" at the shoulder. Additional commentary on the criterion, however, allows for a slightly broader reading. The Secretary also observed that the criterion is intended to advance a definition of SIRVA as a musculoskeletal condition caused by intramuscular vaccine administration into the shoulder, which must include an injury to the shoulder, and excludes a claim for "pain in the neck or back *without* an injury to the shoulder." *Id.* (emphasis added). The criterion is intended to "clearly associat[e]" SIRVA with vaccine injection. *Id.*

Accordingly, claims involving musculoskeletal pain *primarily* occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body. This reading has support in the determinations of other special masters. *Grossmann v. Sec'y of Health & Hum. Servs.,* No. 18-0013V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022) (explaining that the criterion is intended to "guard against compensating claims involving patterns of pain or reduced range of motion indicative of a *contributing etiology* beyond the confines of a musculoskeletal injury to the affected shoulder") (emphasis added).[16] Here, despite the stray notations of pain extending beyond the shoulder, Petitioner's injury is consistent with the definition of SIRVA and there is not preponderant evidence of another etiology.

To the extent that any sequelae deemed not related to the shoulder pain remain a contested issue, those can be resolved in the context of damages.[17]

[15] *See also Dorland's* (defining localized as "not general; restricted to a limited region or to one or more spots").

[16] I have also previously recognized that a petitioner may also be able to distinguish a Table SIRVA from "simultaneous areas of pain due to unrelated conditions," as part of entitlement for a Table SIRVA claim. *Rodgers v. Sec'y of Health & Hum. Servs.*, No. 18-0559V, 2021 WL 4772097, at *8 and n. 16 (Fed. Cl. Spec. Mstr. Sept. 9, 2021). K.P.'s case does not appear to involve any such concurrent conditions.

[17] *See, e.g.*, *Rodgers*, 2021 WL 4772097, at n. 16 (ruling on entitlement, cautioning that the petitioner should draw such distinctions during the damages phase) and 2022 WL 6773160 (Fed. Cl. Spec. Mstr. Dec. 29, 2021) (decision awarding damages).

V. Other Table Requirements and Entitlement

Petitioner has established all other requirements for a Table SIRVA claim. The vaccine administration record reflects the administration site as the left deltoid. Sections 11(c)(1)(A) and (B)(i); Ex. 10 at 44. There is no history of shoulder pain, inflammation, or dysfunction that would explain the post-vaccination injury. 42 C.F.R. § 100.3(c)(3)(i). Her pain began within 48 hours after vaccination. 42 C.F.R. §§ 100.3(a), (c)(3)(ii). There is not preponderant evidence of another condition that would explain the symptoms. 42 C.F.R. § 100.3(c)(3)(iv). Petitioner has not pursued a civil action or other compensation. Section 11(c)(1)(E); Ex. 1 at ¶ 20. Thus, Petitioner has satisfied all requirements for entitlement under the Vaccine Act.

VI. Conclusion and Damages Order

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. **Thus, this case is now in the damages phase.**[18]

Petitioner shall file a status report updating on the parties' progress towards informally resolving damages by no later than Monday, July 11, 2022.[19]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[18] The parties are reminded that in Vaccine Act cases, damages issues are typically resolved collaboratively. Therefore, the parties should begin actively discussing the appropriate amount of compensation in this case. In many cases, damages can be resolved by Petitioners communicating a demand to Respondent, who may agree to the demand or may make a counter-offer.

The parties shall not **retain a medical expert, life care planner, or other expert without consulting with each other and the Chief Special Master.** If counsel retains an expert without so consulting in advance, reimbursement of those costs may be affected.

[19] Petitioner previously sent Respondent a demand and supporting documentation, including a Medicaid lien letter, in March 2020. ECF Nos. 21-23. Respondent responded in May 2020. ECF No. 24.